

SPECBIC.017C3

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Minkow, et al.	) Group Art Unit 3636
Appl. No.	:	09/878,719	RECEIVED
Filed	:	June 11, 2001	NOV 1 9 2002
For	:	BICYCLE SADDLE WIT	н } GROUP 3600
Examiner	:	A. Barfield	,

## DECLARATION OF ROGER D. MINKOW, M.D. UNDER 37 C.F.R. §1.132

- I, Dr. Roger Minkow, having personal knowledge of the facts set forth herein, hereby declare as follows:
- 1 I am a medical doctor and ergonomic designer. Since 1997, I have researched extensively in the areas of male infertility, impotence, and erectile dysfunction and have presented lectures on this topic both in the U.S. and Europe.
- 2. I am aware that Assignee SPECIALIZED BICYCLE COMPONENTS, INC. has filed the above-captioned patent application on a bicycle saddle having certain features that alleviate erectile dysfunction and associated discomfort experienced by cyclists due to the concentration of pressure on the perineal area by a conventional saddle during cycling.
- 3. In cooperation with Dr. Robert Kessler, I have conducted a study of the therapeutic effectiveness of a bicycle saddle ("Specialized Saddle") constructed in accordance with the teachings of the above-captioned patent application and the claims submitted in the Amendment thereof filed March 27, 2002. Specifically, the saddle comprises a rigid frame defining a front end, a back end, a front half, a back half, a first outer side and a second outer side. The frame defines a first support surface at its front end that extends from the first outer side to the second outer side. The saddle generally widens from front to back. The saddle further has a resilient padding layer on top of the frame and has a front end, a back end, a front half, a back half, a first

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outer side and a second outer side. The padding layer defines an upper surface and is continuous from the first outer side to the second outer side at its front end. Additionally, the saddle has a central groove at least partially defined by inwardly facing sides of the resilient padding layer which are beveled toward the upper surface. The groove extends to form a scrotum channel positioned roughly in the longitudinal center of the seat and having a leading edge defined by the resilient padding layer. The groove narrows as it extends toward the scrotum channel along a longitudinal axis from approximately the back of the frame. In at least one embodiment, the leading edge of the groove extends forward to about midway through the front half of the padding layer and provides an open space for relieving pressure on the pudendal arteries. According to another embodiment, the groove is approximately one inch wide at a location midway between the front end and the back end of the frame.

The results of the study were presented at the 1999 annual meeting of the Western Section of the American Urological Association. In the study it was shown that the Specialized Saddle is highly effective in reducing erectile dysfunction and genital discomfort associated with the use of a conventional bicycle saddle. Of 25 male cyclists participating in the study, 23 reported either partial or complete relief of these symptoms after using the Specialized Saddle for one month.

4. The effectiveness of the Specialized Saddle is due at least in part to its shifting of the seating surface (and the cyclist's weight) from a surface underlying the perineal area to one that underlies the ischial tuberosities. This is achieved by removing the longitudinally central portion of the saddle between the ischial tuberosities, resulting in a central cutout and/or groove. To be effective in preventing erectile dysfunction in an adult male, this cutout and/or groove must be of sufficient size to underlie and relieve pressure on the pudendal arteries of a seat occupant. More specifically, the cutout and/or groove must be of sufficient width at the appropriate location, such as about one inch wide at a location that is midway between the front end and the back end of the saddle, to provide an effective therapeutic solution. Moreover, the cutout and/or groove must also be of sufficient length, such as extending forward to about midway through the front half of the padding layer. Such a cutout and/or groove has been shown to be therapeutically effective by preventing any portion of the saddle from exerting pressure on the perineal area and the pudendal

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arteries. Saddles with a narrower and/or shorter cutout and/or groove have not been proven to alleviate erectile dysfunction.

- 5. I have reviewed U.S. Patent No. 576,310 to Henderson, U.S. Patent No. 594,451 to Wheeler, and the advertisement of the ISCA Plus saddle, all of which were cited as prior art during prosecution of the above-captioned patent application.
- 6. None of the Prior Art Saddles incorporate a cutout or groove of a proper size to alleviate erectile dysfunction in male cyclists. Specifically, the Henderson patent discloses a bicycle saddle with a central depression that, given the apparent scale of the drawing, appears to be approximately one-half inch wide at a location midway between the front end and the back end of the frame. Such a groove is thus too narrow to be therapeutically effective with regard to erectile dysfunction. The Wheeler patent discloses a bicycle saddle with a central groove that, given the apparent scale of the drawing, appears to be approximately .75" to 1" in width at the rear, and then widens before it narrows to the leading edge. Accordingly, the Wheeler groove does not narrow as it extends forward from the rear of the frame. Such a groove is thus also too narrow to be therapeutically effective at relieving pressure on the pudendal arteries. Finally, the saddle shown in the ISCA Plus advertisement has a cutout/groove that is far too narrow and too shallow to provide the benefits of the Specialized Saddle with respect to erectile dysfunction.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

11/06/02— Dated:	By: 16/1
	Dr. Roger. D. Minkow